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EXAMINER

FAY, ZOHREH A

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/046,575  
Filing Date: January 16, 2002  
Appellant(s): NISHIMUTA ET AL.

**MAILED**  
**NOV 29 2007**  
**GROUP 1600**

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Christopher L. North  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed August 20, 2007 appealing from the Office action mailed February 20, 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

Fleischer, Alan B., "treatment of atopic dermatitis: role of tacrolimus ointment as topical noncorticosteroidal therapy" *Journal of Allergy and Clinical Immunology* (1991), 104 (3, pt. 2), S126-S130.

Miller, J.J.; "Effects of simple imidazoles on human peripheral blood lymphocytes stimulated by mitogen or allogenic cells", *Journal Immunopharmacology*, (1980) 2/2 (225-243).

#### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 13, 14 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (WO 98/27960) in view of Fleischer (1999, abstract only); or Fleischer (1999) and Miller et al. (1980, abstract only).

Goodman et al. teach a viscous hydrogel composition containing nitroimidazole (e.g. tinidazole) for treating inflamed skin disease such as rosacea and eczema, see the abstract and page 1, lines 12-15, especially example 1. The specie, tinidazole in a therapeutically effective amount about 0.75% is well taught and encompassed by scope of the claims.

Applicant's claims differ from WO patent because they specifically require treatment of atopic dermatitis.

However, it would have been obvious to a person skilled in the art to substitute the inflamed skin diseases of WO with atopic dermatitis when WO is taken in view of Fleischer (199) or Fleischer and Miller (1980) together because later references, teach deficiencies in Goodman et al.'s teaching. Fleischer teaches that atopic dermatitis is a form of eczema. Fleischer also teaches that immune regulation plays an important role in the cause of atopic dermatitis. Miller teaches that tinidazole is effective immunosuppressant in vivo. See the abstract.

Thus, one skilled in the art would have been motivated to prophylactically treat atopic dermatitis using tinidazole, because treating eczema could prevent further undesirable implications (e.g. relapsing or transforming into chronic eczema) which can become atopic dermatitis, considering that tinidazole is proven to be an effective therapeutic modality for eczema or other inflamed skin diseases. If immune regulation were considered to be the underlying mechanism of atopic dermatitis, one would have been motivated to make such substitution with the assurance of reasonable expectation of success, considering that Miller teaches that tinidazole as an effective immunosuppressant in vivo.

One would have been motivated to do so, with the reasonable expectation of success, because it is considered to be desirable to have extended therapeutic modalities to improve patient compliance by enhancing patient satisfaction and increasing the selection option.

These references are particularly pertinent and relevant, because all the claimed species and their roles are well taught in the cited references when they are combined together. Thus, one would have been motivated to combine these references and make the modification because they are drawn to the same technical fields (constituted with the same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. See MPEP 2141.01 (a).

#### **(10) Response to Argument**

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant in his remarks refers to WO'817 trying to establish

that there are different types of eczema. The arguments are noted, however such arguments will not overcome the prior art rejection. The prior art clearly teaches that the claimed compounds have been previously used for the treatment of eczema in general. Fleischer et al. teach that atopic dermatitis is a form of eczema. Fleischer et al. also teach that immunosuppressant agents are effective in treating atopic dermatitis. Thus, it would have been obvious to a person skilled in the art to use a compound being used for the treatment of eczema in general and use it for the treatment of atopic dermatitis. The fact that WO'817 teaches that the claimed compounds have been previously used for the treatment of one type of eczema does not mean that it cannot be used for the treatment of any other types of eczema or atopic dermatitis. In conclusion: Goodman et al. teach the use of the claimed compounds for the treatment of eczema. Fleischer et al. teach that atopic dermatitis is a form of eczema, and immunosuppressant agents, such as tacrolimus can be used for the treatment of atopic dermatitis. Miller et al. teach that tinidazole has immunosuppressive activity. It would have been obvious to a person skilled in the art to use the claimed compounds for the treatment of atopic dermatitis, considering that the prior art teaches atopic dermatitis is a form of eczema and eczema has been treated by the claimed nitroimidazole compounds. The addition of the secondary compounds, such as immunosuppressant agents to the composition of primary reference, would have been obvious to a person skilled in the art considering that Fleischer et al. teach immunosuppressant compounds, such as tacrolimus have been previously used for the treatment of atopic dermatitis.

The combination of ingredients with the same character is merely the additive effect of each individual component.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

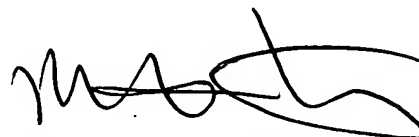
/Zohreh Fay/



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